S. HRG. 109–193

[ERRATA]

ROUNDTABLE DISCUSSION: WHEN TERROR STRIKES—PREPARING AN EFFECTIVE AND IMMEDIATE PUBLIC HEALTH RESPONSE

HEARING

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

ON

EXAMINING AN EFFECTIVE AND IMMEDIATE PUBLIC HEALTH RESPONSE IN THE AFTERMATH OF A TERRORISM ATTACK

JULY 14, 2005

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Supplemental Prepared Statements of George Barrett and George Conk and Response to Questions by Leah Devlin and Tara O'Toole were submitted for the above referenced publication. The additional material follows.

ADDITIONAL MATERIAL

PREPARED STATEMENT OF GEORGE BARRETT

Chairman, members of the committee, my name is George Barrett, President and CEO of Teva North America.

First, I wish to thank you for inviting Teva to participate in this Roundtable discussion today on such an important topic.

Teva is a vertically-integrated global pharmaceutical company founded in Israel in 1901, and is the second largest pharmaceutical manufacturer in the United States based on numbers of prescriptions dispensed. Teva North America is headquartered in North Wales, Pennsylvania and has United States manufacturing facilities located in several States. With more than 230 products on the U.S. market, Teva manufactures approximately 1 out of every 16 prescriptions dispensed in the United States. Additionally, Teva is one of the largest producers of anti-infective agents in the United States.

Teva holds a unique position from which to view the bioterrorism discussion. Although Teva is best known as the U.S. market's largest generic player, we are also a developer and manufacturer of patented, researched-based pharmaceutical products—we produce and market the leading pharmaceutical product for the treatment of Multiple Sclerosis. Because of our dual role, we have a deep appreciation for the fine balance between encouraging innovation and ensuring access to affordable medicines.

It is also worth noting that, because our parent company is headquartered in Israel, we have a particular familiarity with the threat of terrorism and regard today's discussion with the utmost seriousness.

We at Teva share a deep commitment to ensuring that the United States is well-prepared to counter a bioterror attack. Teva strongly supports initiatives designed to bring more rapidly and efficiently produced pharmaceutical products to counter a bioterrorism attack. Indeed, we believe that S. 3 and S. 975, as introduced this year, contain some commendable and workable provisions that provide substantial incentives for pharmaceutical companies to respond to the challenge of producing needed countermeasure pharmaceutical products. These include tax credits, needed product liability relief, and direct grants.[1]

What Do These Promising Proposals Have in Common?

Broadly speaking, the promising aspects of these 2005 bills have four key characteristics in common. Specifically, these provisions are (1) **transparent**, (2) **proportional**, (3) provide linkage between the incentive and the relevant investment, and (4) allow continued **timely access to affordable generic versions of life saving drugs to the people who need them most—the sick and the elderly**. By transparency, we refer to a process which is clear and economically visible and predictable. By proportional, we mean the benefits should be commensurate with the effort. Any further legislative incentives must, in our view, reflect these four key characteristics which Congress embraced in Bioshield I.

Unfortunately, in our view, some of the additional incentives proposed in S. 3 and S. 975—specifically the "wild card" patent term extension provisions, the new patent restoration provisions, and the proposed expansion of existing regulatory exclusivity periods—fail to reflect these characteristics and would erode the carefully crafted balance struck by Congress when it passed the Hatch-Waxman amendments. The effects of these harmful proposals will be felt by American consumers through increased health care costs in the United States. More specifically,

- The proposed "special patent term extension," commonly referred to as the "wild card extension," would extend a patent for up to 2 years on any patent of the drug company's choosing—even those products wholly unrelated to any bioterrorism coun-

[1] *See* S. 975, 109th Cong. §§311–312, 341 and *passim* (2005), respectively; S. 3, 109th Cong. §§151–152, 131–142, and *passim* (2005), respectively.

termeasure.[2] Any proposal of this sort fails all four tests in that it lacks transparency, proportionality, and linkage, and would delay generic access for potentially scores of crucial drug products. The result would be to dramatically increase the cost of health care in this country, and place the added cost burden disproportionately upon the sick and elderly. We urge Congress to reject any wild card extension proposal as it moves forward with Bioshield II legislation.

• The pending bills would also add new patent extension restoration incentives.[3] These proposals also lack transparency, linkage, and proportionality, and would, by their nature, further delay access to affordable generic drugs. For example, the proposed extension mechanisms do not include any of the carefully balanced limitations of the current pharmaceutical patent term restoration law—specifically the 5-year cap[4] on any restoration and the 14-year cap[5] on the total effective patent term after a restoration.[6] Moreover, contrary to existing law, these extensions would give full credit for time spent prior to submission of a New Drug Application for a product, thus diluting the incentive to proceed expeditiously in developing a product for submission to FDA for approval.[7] Thus, this policy could substantially increase the costs of pharmaceutical products to consumers and both public and private payers. These proposals should also be rejected by Congress, but at a minimum must restore carefully crafted Hatch-Waxman limitations[4 5 6] and would need to be substantially reworked to provide clear and direct linkage of the extension to the actual development and deployment of truly novel countermeasures. Furthermore, the truly novel countermeasure should pass two tests: (1) it should be required to show clinical superiority to existing countermeasures and (2) it is unique, i.e., there is no other practicable countermeasure readily available.

• One pending bill, S. 975, would, in certain circumstances, double the length of the existing 5-year New Chemical Entity ("NCE") exclusivity and the 3-year "clinical trial" exclusivity, and would expand the 7-year Orphan Drug Exclusivity to 10 years.[8] This proposal is highly disproportionate to the effort needed to qualify for these extensions, suffers from a lack of transparency, and would substantially delay access to affordable medicines. Any proposal of this nature should therefore also be rejected.

I would like to add that one should look with suspicion at any proposal that seeks to use the threat of trade sanctions as a way of forcing patent extensions and data exclusivity provisions on a non-domestic pharmaceutical producer, which would lead to the unintended result of increased pharmaceutical prices for American consumers.[9]

It is in this context that we regard certain provisions of S. 3 and S. 975 as inconsistent with the goal of bringing novel countermeasures to the market, while at the same time preserving access to affordable medicines. Each of these bills contains harmful incentives which disconnect the rewards from the investment. As introduced, certain provision of these bills would have the unintended effect of delaying generic drugs to market and increasing health care costs in the United States.

Of the annual $235 billion spent in 2004 on prescription drugs in the United States, the generic segment accounted for only about 10 percent of the costs. This is true, despite the fact that over 50 percent of the prescriptions were filled with a generic pharmaceutical product. Consumers, businesses, health plans, and the Government all benefit from the availability of generic pharmaceuticals. Any delay in the flow of generic products into the market will have a crippling cost impact on American private and public purchasers and a disproportionate affect on society's most vulnerable. Clearly, this is a result that America can ill-afford at this time.

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[2] *See* S. 975, §§ 301(b)(4)(A)(iv), 332; S. 3, § 113(d).

[3] *See* S. 975, § 331(b); S. 3, § 113(c).

[4] *See* 35 U.S.C. § 156(g)(6)(A) ("If the patent involved was issued after the date of enactment of this section, the period of extension determined on the basis of the regulatory review period determined under any paragraph may not exceed five years.").

[5] *See* 35 U.S.C. § 156(c)(3) ("[T]he period of extension shall be reduced so that the total of both such periods does not exceed fourteen years.").

[6] *See* 37 C.F.R. § 1.775(d).

[7] *Compare* S. 975, § 331(b) (proposing 35 U.S.C. § 156a(b) ("The term of an eligible patent shall be restored by a period equal to the number of days in the regulatory review period[.]")); and S. 3, § 112(c) (proposing 35 U.S.C. § 156a(b)(same)) *with* 35 U.S.C. § 156(c)(2) (reducing the period of time eligible for extension based on the review of the Investigational New Drug Application to one-half day per day).

[8] *See* S. 975, § 331(e).

[9] *See*, e.g., S. 975, § 332 (stating that the Secretary of Commerce, the United States Trade Representative and the Commissioner of Patents shall ensure that "substantially similar intellectual property rights granted to the same or related entities as those that qualify for restoration or an extension under such sections are not impaired.").

What Approach Should Congress Consider in Pursuing Bioshield II Legislation?

Congress should consider the role of pharmaceutical manufacturing in the biodefense effort in the broadest of ways. This requires not only that we encourage the development of novel treatments with *appropriate* incentives, but also requires that we pay particular attention to procuring the appropriate products in the fastest way possible.

Much of the public discussion has centered around encouraging the "major" research-based pharmaceutical companies to engage in this activity working on countermeasures. Yet today, three of the five largest producers of pharmaceutical products in the United States are "generic drug" companies. Another company among the top five has a very large generic pharmaceutical division. These are companies with enormous productive capacity, multipurpose facilities, and extensive distribution operations, and as a result, high operational flexibility. Teva alone produces and distributes well over 200 generic products for the U.S. market and is one of the world's largest producers of anti-infective agents. We would encourage you to consider how to mobilize our Nation's entire productive capacity to help counter a bioterror threat.

Legislation should focus more closely on the production, procurement, and distribution aspects of a bioterror response system. Part of that system should include mechanisms for rapid technology transfer to manufacturers where a needed countermeasure is in short supply or cannot be produced by the company that may be the sole current producer. Companies like Teva have the capacity and flexibility to respond to this need and can begin producing large quantities of pharmaceuticals on short notice. However, the normal regulatory procedures used to qualify a new manufacturing site are time consuming, which could delay emergency access. Expedited regulatory pathways for such manufacturing site changes are necessary to assure rapid response to any bioterror attack.

Congress should, in much the same way it procures military equipment in a time of war, establish a direct procurement system as part of the defense budget to obtain needed pharmaceutical countermeasures. This would build on the work of Bioshield I, with companies bidding on contracts to provide specifically requested countermeasures at negotiated prices. We strongly advise that Congress add a guaranteed stockpile purchasing component to this direct procurement system.

We believe that participation in the cost of clinical trials would be the most direct and appropriate incentive to encourage the development of novel countermeasures. The risk associated with clinical trials is the largest cost a company faces in evaluating a pharmaceutical development project. We would recommend that Congress include clinical costs in procurement contracts. Direct support for clinical trials would be a fair and workable system and would help support the goal of encouraging the development of countermeasures. Indirect subsidies, such as patent/exclusivity extensions, will undermine the ultimate objective.

Finally, we have a policy recommendation to help rapidly identify and widely disseminate information on drugs known to be effective against many potential bioterror weapons. Specifically, a "Medical Expert Biodefense Task Force" should be established to review data relating to available drugs, biologics, antibiotics, and devices that may be effective in treating, preventing, identifying, or detecting harm from potential bioterror weapons. This information would then be used by the Department of Health and Human Services Secretary to immediately inform health care prescribers of the currently available products that are suitable for treating or responding to bioterrorism health threats, thus expediting the range and use of treatment options available for health care professionals and patients. By reviewing available medical literature to identify bioterror pathogens and agents for which reliable evidence exists as to the efficacy of existing treatments, America's security could be quickly and cost-effectively enhanced—without the need for unnecessary and cost inefficient intellectual property-based incentives.

Preparing our Nation to respond to a bioterrorism threat will not come without a significant Federal investment. It is far better, however, to have a direct system of procurement paid for out of the defense and homeland security budgets (with the burden falling equitably among all Americans), than to create a far more expensive and elaborate, loophole-laden patent or exclusivity incentive scheme that shifts the cost onto the health care system. A direct system would successfully, efficiently, and cost-effectively encourage the pharmaceutical industry to provide needed countermeasures.

Teva will continue to support measures which encourage the development of novel biodefense countermeasures, among them tax incentives related to development and manufacturing, product liability relief, research and development grants, guaran-

teed stockpile purchasing, and other approaches as described above. Such approaches would be consistent with the essential characteristics of transparency, proportionality, and providing linkage between the incentive and the relevant investment without compromising America's access to affordable medicines on a timely basis.

Finally, Teva is prepared to do its part in this overall biodefense effort.

Thank you, Chairman, members of the committee, for allowing Teva to share our thoughts with you today.

PREPARED STATEMENT OF GEORGE W. CONK

Introduction

S. 975, the proposed "Project BioShield II Act of 2005," broadly addresses "biological and chemical agents, toxins, and nuclear and radiological materials that may be used as weapons of mass destruction **or** that are infectious diseases with respect to which the Secretary finds that research to develop new and improved countermeasures is in the national interest of the United States."

Biodefense as protection against terrorist attack is properly seen as but a part of a comprehensive plan to protect and improve the public health system. We cannot say if or when we will be attacked with biological weapons. But our experience with HIV and SARS, immigration, and international travel enable us to say with certainty that new pathogens will present major challenges to our public health system.

Naturally-occurring biological threats and criminal attacks (whether political or otherwise) using biological and other such weapons closely overlap in the pathologies inflicted and in the human and material resources needed to respond effectively. Biodefense against terrorists is but a subset of our overall public health preparedness. As the Institute of Medicine said after the recent smallpox vaccination campaign: "Readiness to respond to public health emergencies (including smallpox [and other] emergencies) should be part of overall continuous quality improvement of the public health system." [1]

Our approach to civil liability and victim compensation too should generally treat alike compensation issues arising from general public health measures and "biodefense" against criminal use of pathogenic biological agents. We need not overhaul our system of compensation and liability—but should adjust it to address specific shortcomings. But S. 975 unwisely federalizes a wide swath of our public health system. The United States would gratuitously insure a wide swath of industry, researchers, hospitals, and health care workers. S. 975 substitutes the United States in their stead as defendant in an unknowable number of cases, displacing State common law with Federal limits on damages, and eliminating the common law right to trial by jury which is preserved in every State.

We rely on three main approaches: tort liability (including product liability), workers compensation, and statutory compensation schemes for special needs. Among the special needs cases are the childhood vaccine compensation program which addresses complications arising from mandatory vaccination,[2] and the smallpox vaccination program in which we asked health workers to volunteer to subject themselves to a live virus which carried a risk of vaccine-related disease in the recipients.[3] Thirty years ago we enacted a special measure for swine flu vaccinees.

We should adhere to the State law based common law tort system and workers compensation as the principal sources of compensation, offering out-of the ordinary compensation only exceptionally, such as to those who volunteer to subject themselves to extraordinary risks.

The Federal Government should not gratuitously insure "biodefense" manufacturers, distributors and administrators for their negligence. S. 975's broad expansion of such undertakings is unwarranted.

Our priorities in public health defense must be to:

- maximize the health of the American people;
- ensure public confidence that government is making its best efforts to protect the health of all who live in, work in, and visit America; and
- recognize that public trust requires both candor and acceptance of responsibility for error.

The Tort System and Product Liability Law

One who through his fault causes harm to the person or property of another is liable in tort. One who employs a negligent person is responsible for the harm caused by the negligence of his/her employee. Product liability law has often been described otherwise—as strict or even absolute liability. But product liability law

has grayed, as leading treatise author Prof. David Owen has observed. It is a mature body of law which yields generally predictable outcomes.

The basic propositions of our product liability law are these:

- when products depart from specification and cause injury to others the manufacturer of the product bears responsibility for the harm caused by its departure from the norm;
- manufacturers must exercise stewardship over their products—studying them sufficiently that users and others are given sufficient information to use them safely, and to make a reasonable assessment of those risks which unavoidably accompany use of a worthwhile product; and
- manufacturers are responsible for the harm done by negligent design—the unreasonable omission of practical and feasible safer alternative designs.

These principles express deeply embedded normative expectations of our citizens. Federal, State and local government, individuals, and industry accept similar responsibility for their errors. A heavy burden of persuasion therefore should be imposed on those who favor immunity or limited liability for designers, manufacturers, researchers, and administrators of vaccines and other biological, pharmaceutical, and medical products.

The employer-funded workers compensation system plays a major role in protecting health and emergency workers. Injuries arising out of and in the course of employment are compensable regardless of fault. Only a causal connection between the work and the illness need be shown.

The tort and workers compensation systems are capable of (and do) handling the needs of those injured. They adequately limit the liability risks of those who undertake to do the research, develop, and deploy the technologies which the Congress seeks to encourage. And they do it without relieving actors of liability for their faulty conduct and without the Federal Government gratuitously assuming liability for harms it did not create.

Free Insurance and Limited Liability

In the past 25 years I have represented those injured by asbestos products and machine sellers who did not exercise reasonable stewardship over their products. Tort liability was properly imposed. In my representation of hemophiliacs and their families I saw that an industry immunized by "blood shield laws" escaped liability despite its failure to pasteurize blood products which were given to hemophiliacs. Nearly every hemophiliac in America, Western Europe, and Japan was infected with HIV and/or hepatitis as a result.[4]

Of the three epidemics the legal system dealt far more justly with asbestos and industrial accident than it did with hemophiliacs. I therefore view very skeptically those who would shift to the public the cost of compensating those who have been injured by a manufacturer's negligent (or more egregious) conduct.

Such a shift would be the result of S. 975. The bill relieves of responsibility for their errors manufacturers, distributors, and administrators of "biodefense" and other public health measures. It insures the negligent without charge and offers limited compensation to victims of medical and industrial error who can prove fault by the immunized in whose place the United States stands. S. 975 is a legislative massive expansion of Executive Order 10789 contractual indemnification by Government coupled with a thin compensation program modeled on the 2003 Smallpox Emergency Personnel Protection Act of 2003, which amended the Public Health Service Act.[5]

This expansion of aspects the Smallpox Emergency Personnel Act is undertaken without study of its cost. If the cost proves to be small and industry's fears are unwarranted, the expansion of Federal responsibility is unneeded. If the cost is shown to be large then candor and fiscal responsibility require that we make provision for that budgetary burden. If we lack adequate information we should not act.

False Alarms

Fears are expressed that incalculable, and impliedly huge, liability is faced by "biodefense" manufacturers. I believe these fears are unwarranted and do not justify the proposed broad expansion of the defense, indemnification, and compensation scheme adopted in the Smallpox Emergency Act. Nor is it necessary for the United States to assume the burden of defending, as it would public health officers in its employ, all who "manufacture, distribute and administer" "biological and chemical agents, toxins, and nuclear and radiological materials that may be used as weapons of mass destruction or that are infectious diseases with respect to which the Secretary finds that research to develop new and improved countermeasures is in the national interest of the United States."

Last October this committee was warned that "a test kit for Anthrax exposure that may, perhaps, provide false positives would expose the manufacturer to tremendous and likely (un)insurable liability thereby preventing widespread deployment, even if the diagnostic is the current state-of-the-art." No such liability risk exists.

HIV tests have recognized rates of false positives. The test is therefore administered twice, since consecutive false positives are rare. No liability problems have ensued. If by "state-of-the-art" one means current practice, liability is not categorically ruled out. But a legal presumption that FDA approval indicates reasonableness in design and warnings is common.[6] Such a presumption must be rebutted by competent evidence that critical safety information was unreasonably omitted or not developed, or that a safer alternative design was practical, feasible, and unreasonably omitted.

Others have suggested that those who have obtained approval for emergency measures—such as distribution of a biologic that has been tested only on animals, and allowed to be distributed as an emergency measure, after findings of specific threats at the Secretarial level and FDA approval under 21 U.S.C. 360bbb-3 need special protection from liability claims. But the law of torts is founded on a determination of reasonable risk imposition—and an emergency is an appropriate circumstance for taking risks in rescue efforts that otherwise would not have been taken.

In almost every jurisdiction the Second Restatement of Torts § 402 A, comment K would be cited for the proposition that an unavoidably unsafe but useful product is not defective if it is administered with reasonable care, and the patient is given reasonable notice of the dangers presented by the product (either directly or by informing the prescribing physician), and the good done by the product exceeds the harm it causes. The factual determination of necessity by the Secretary of Defense and Secretary of Homeland Security of a specific threat and FDA approval of such a product are all powerful indicia of reasonableness and necessity. Administration of such emergency medications, with adequate advice to recipients, is certainly reasonable and therefore is not actionable—under common law tort principles.

It has also been suggested that vaccines which cannot ethically be deployed in clinical trials because of their hazards present grave liability risks for manufacturers who can test them only on animals and therefore may not be able to identify risks to humans. Such limitations of evidence are but a factor for the FDA and others to consider in determining safety and effectiveness. If such risk is unavoidable for ethical or other reasons, then use of such products is reasonable and non-actionable. In fact the archetypal example taught to every law student is the unavoidable risks of the Pasteur rabies vaccine which faced a patient with the choice of risking a horrible death from rabies if the animal was rabid, or taking the risk of taking the unavoidably unsafe vaccine. Such products are not defective—every law student learns.

Who has Potential Claims? How Are They Treated? How Should They Be Treated?

Under existing law potential claimants include:

1. Persons who while in the course of their employment work with infectious materials or persons, toxic materials, or devices and who suffer illness or injury (such as health workers exposed to HIV or tuberculosis). Such workers are entitled to workers compensation benefits. And in the case of injury by a defective product, or inadequate warning they have a right to bring a third party product liability suit. The present system is adequate.

2. Persons who volunteer to administer vaccines or render medical care to others who become ill or suffer injury because of their care for others. Such persons are not compensated, except if a fault-based tort action is available. Such persons should be compensated either by workers compensation or by a no-fault system of compensation such as Congress devised for those who administered or received smallpox vaccination.

3. Volunteers who offer to be vaccinated as part of preparation for service to others (e.g., medical personnel who volunteered to be vaccinated against smallpox). Such volunteers are not compensated unless they assumed the risk at the request of their employer and the risks arise from the employment. Pure volunteers should be compensated via a no-fault system. Common law product liability actions should be retained.

4. Volunteer subjects in clinical trials. No provisions exist for compensating such volunteer subjects. Compensation—including medical care should be afforded for such persons.

5. Persons who are compelled to be vaccinated (such as children who cannot be admitted to school unless they are vaccinated). Children who suffered recognized complications (or provable complications) are entitled to be compensated under the National Childhood Vaccine Injury Compensation Act of 1986. Persons compelled to take such risks should be compensated.

6. Patients who, to protect their health, are vaccinated voluntarily and become sick thereby. Such persons do not receive compensation and should not be compensated unless the product was defective or the medical advice was unreasonable.

7. Household members or others who become sick through contact with dangerous materials, infected persons, or the like (such as intimate contacts of smallpox vaccinees). They are compensated only through tort actions—which are generally not available. Even if the physician who ordered the vaccination knew of the risk to the household member and failed to warn of it, an action is not viable absent a physician-patient relationship. The extent of the duty of a physician is best left to developing common law tort law.

Compensation Choices

BioShield I immunized smallpox vaccine manufacturers by compelling all claims to be made against the United States under the Tort Claims Act—allowing recourse against the manufacturer only for gross misconduct or contract violation. S. 975 permits (limited only by unreviewable administrative fiat) broad expansion of that burden to an "initial list" of 75 agents of disease, and "(a)ny other new and emerging natural infectious disease threats."[7]

Why should the United States, if it chooses to assume such a burden as insurer, do so without fee? And why, in any event, should it limit its right to recover from its suppliers to instances of breach of contract or gross misconduct? Why should the United States—if it chooses to compensate citizens for the wrongful conduct of independent contractors—not retain the right of recovery from those whose negligence or defective products caused injury? In my view the United States should not gratuitously insure manufacturers, distributors and administrators of defective products and those who act negligently.

Endnotes

1. IOM, Review of CDC Smallpox Vaccination Program Implementation, Letter Report 5, January 22, 2004.

2. 42 U.S.C. 300aa-15.

3. 42 U.S.C. 239.

4. B.L. Kroner, et al., *HIV-1 Infection Incidence Among Persons with Hemophilia in the United States and Western Europe*, 1978–1990, Journal of Acquired Immune Deficiency Syndromes, 7:279–286 (1994); Institute of Medicine of the National Academy of Sciences, HIV AND THE BLOOD SUPPLY, National Academy Press (1995).

5. 42 U.S.C. § 202.

6. Perez v. Wyeth Lab., 161 N.J. 1 (N.J., 1999).

7. S. 975, § 319F-3 (f).

Resources

George W. Conk, *Reactions and Overreactions: Smallpox Vaccination, Complications, and Compensation*, 14 Fordham Environmental Law Journal 439 (2003).

George W. Conk, *Is There a Design Defect in the Restatement of Torts: Products Liability?*, 109 Yale L.J. 1087 (2000), and George W. Conk, *The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market*, 49 UCLA L. Rev. 737 (2002) (arguing that drugs, vaccines, blood products, and medical devices are amenable to the alternative safer design test of product defect embraced by Section 2 of the Products Liability Restatement, [ALI 1998] and rejecting the Restatement's Section 6(c) which rejected such a comparative test, permitting liability findings only where the sum of the harms done by the product exceed its benefits for every class of user); but see James A. Henderson, Jr., and Aaron D. Twerski, *Drug Designs* Are *Different*, 111 Yale L.J. 151 (2001) (acknowledging the aptness of testing by alternative designs, but limiting the comparison to products already approved by the U.S. Food and Drug Administration and actually available on the market at the time of sale of the challenged product).

Comment K and defense of Drug Product Design Claims:

Some courts have construed Restatement of Torts, 2d, § 402A, comment k to be a rule of virtual immunity for drugs, which are presumed to carry risks that are unavoidable. See, e.g., *Brown* v. *Superior Court (Abbott Labs.)*, 751 P.2d 470 (Cal.

1988); *Grundberg* v. *Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young* v. *Key Pharms.*, 922 P.2d 59 (Wisc. 1996) (en banc).

Support for the Brown approach appears to be eroding. See, e.g., *Freeman* v. *Hoffman LaRoche*, 618 N.W. 2d 827 (Neb. 2000) (Supreme Court overrules *McDaniel* v. *McNeil Labs. Inc.*, 241 N.W.2d 822 (Neb. 1976), and rejects its previous adherence to the minority view that a properly manufactured drug accompanied by an adequate warning of the risks known to the manufacturer at the time of sale is not defectively designed as a matter of law). Accord: *Bryant* v. *Hoffman La Roche*, 2003 Georgia Lexis 945 (Ga. Ct. App.).

The Nebraska court now embraces the "majority rule" that applies the comment k defense on a case-by-case basis, believing that societal interests in ensuring the marketing and development of prescription drugs will be adequately served without the need to resort to a rule of blanket immunity. See, e.g., *Tobin* v. *Astra Pharm. Prods., Inc.*, 993 F.2d 528 (6th Cir. 1993); *Hill* v. *Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989); *Belle Bonfils Mem'l Blood Bank* v. *Hansen*, 665 P.2d 118 (Colo. 1983) (superseded by statute in regard to blood banks, as recognized in *United Blood Servs.* v. *Quintana*, 827 P.2d 509 (Colo. 1992)); *Ortho Pharm. Corp.* v. *Heath*, 722 P.2d 410 (Colo. 1986), overruled on other grounds by *Armentrout* v. *FMC Corp.*, 842 P.2d 175 (Colo. 1992); *Toner* v. *Lederle Labs.*, 732 P.2d 297 (Ida. 1987); *Feldman* v. *Lederle Labs*, 479 A.2d 374 (N.J. 1984); *Castrignano* v. *E.R. Squibb & Sons, Inc.*, 546 A.2d 775 (R.I. 1988).

The Third Restatement of Torts, Product Liability, § 6 (c) holds that design defect claims can be brought against prescription drug and medical device manufacturers only if the drug provides no "net benefit" to any class of users.

The Restatement (Third) of Torts: Products Liability, § 2 (b) provides that a product is defective if a "reasonable alternative" safer design was "unreasonably omitted."

Response to Questions of the Committee by Leah Devlin

An important role for the Federal Government is to work collaboratively to assure a stable, predictable market for biodefense medical countermeasures and to address related liability issues. Public health, with an adequately built and maintained infrastructure, can then guarantee timely distribution of these countermeasures to ultimately protect the American population from preventable illness and death.

The three main strategies needed to maintain a robust public health infrastructure are a commitment to an all hazards approach, a trained workforce, and sustainable funding. These three factors, commitment, people and resources, will see the Nation into a safer, more protected, and better-prepared future.

The multiple agencies and industries involved in the food chain must integrate and coordinate their surveillance, risk vulnerability, and mitigation plans. Human health, livestock and crop protection must be viewed as a single system for the development of surveillance systems, standardized plans, and training for local, State, Federal, and industry stakeholders.

Question 1. What additional incentives or other measures will ensure the timely availability of sufficient amounts of effective biodefense medical countermeasures, and is the cost of such incentives acceptable?

Answer 1. Biodefense medical countermeasures are one essential component of an effective preparedness and response effort which must also include surveillance, early detection, quarantine, isolation, distribution of biodefense medical countermeasures including mass vaccination, mass care and public communications. Having said this, at this critical point in history, the alignment of incentives in the production of biodefense medical countermeasures (mainly vaccines and anti-infective drugs) must hinge on the ability of Government, business, and public health to adequately plan together for these exigencies. This fundamental concept will be articulated using the examples of pandemic influenza, a natural event, and the dispersal of anthrax spores, a deliberate event.

An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in simultaneous epidemics worldwide with enormous numbers of deaths and illness. Because of the ongoing and unprecedented spread of highly pathogenic avian influenza type H5N1 in SE Asia, the global alarm for the next human influenza pandemic has been sounded by the WHO. The toll in the United States using a mid-point estimate of a 25 percent attack rate and a 5 percent mortality rate would result in 3 million deaths and 10 million hospitalizations, 10 to 100-fold greater than the numbers experienced during a typical wintertime flu season. Presently, the only biodefense countermeasure for an H5 pandemic influenza of avian origin from SE Asia is the single antiviral drug, oseltamivir (Tamiflu®). The U.S. Strategic National Stockpile contains only a small

fraction of the oseltamivir needed to protect the U.S. population. Using current biotechnology, it would take 12–18 months into the pandemic for a suitable vaccine, the ideal biodefense countermeasure, to be developed, scaled-up, and delivered.

In October 2001, the United States fell victim to a bioterrorist attack using weaponized anthrax spores. This limited attack on the U.S. mail system resulted in 23 cases and 6 fatalities. A terrorist release of anthrax spores delivered from a small airplane upwind of a city of 1 million inhabitants could result in 125,000 cases and 95,000 fatalities, the first cases arising within 3 days and as long as 2 months following dispersal. The ideal biodefense countermeasure is early detection allowing a rapid public health response including delivery of protective antibiotics or vaccination to the exposed population. Ironically, supplying and delivering protective antibiotics and/or vaccine to a large population at risk within the 3-day incubation period for anthrax would be difficult without sustained investment in the public health infrastructure.

These two natural and deliberate infectious disease disasters are not far-fetched scenarios. The natural history of humankind predicts 2–3 influenza pandemics every century and the events of 2001 showed that our Nation is vulnerable to an anthrax attack. What incentives, then, are required at an acceptable cost that will ensure timely, sufficient and effective biodefense countermeasures? Planning among Government, business, and public partners is essential to assure a stable, predictable market for biodefense medical countermeasures and to address related liability concerns.

In last year's influenza season, the collaboration between industry and Government was commendable. It is vitally important when vaccines or other countermeasures are in short supply and the need is great that the Federal Government and industry work together through the State and local public health infrastructure to assure maximum health protection for the public.

Question 2. What is necessary to build and maintain a robust national public health infrastructure to meet future biodefense requirements?

Answer 2. Prior to 9/11 public health's preparedness efforts had been focused on time-honored communicable diseases and traditional investigation strategies as well as responding to natural disasters such as hurricanes to the extent possible. Many times an effective public health response meant dropping everything else from infant mortality reduction efforts to the prevention strategies targeting chronic diseases, the leading causes of death, just to get through the outbreak or natural disaster.

After 9/11, public health was fully recognized for the first time for its critical role as a first responder, a vital part of the community's response to an intentional or unintentional chemical, biological, radiological, nuclear or explosive (BCRNE) attack. The new normal for public health is that preparedness is a core function. The States have a central role in assuring that every county and every local health department are prepared to respond effectively. It is critical to recognize that ALL emergencies will be identified and first responded to on a local level and that the State will mount a multi-county or statewide effort to support this initially local response. The Federal Government comes in to assist the States as needed. This coordinated local, State and Federal public health response represents one system in responding effectively to any event that threatens the public's health. And clearly critical, new partnerships have been created between public health and agriculture, law enforcement, emergency management, emergency medical services, other first responders of all types and other medical providers in order to have the greatest impact. These partnerships with public health have become institutionalized and are absolutely critical to saving lives in every community in the Nation.

The top three priorities to maintain a robust national public health infrastructure are to:

1. Focus on All Hazards—but at the same time remember that public health is much broader than preparedness.

2. Assure a workforce that has the expertise to respond effectively in a world of new challenges—S. 506 (Hagle/Durbin) bill should be passed.

3. Sustain a national commitment to the Federal preparedness cooperative agreement funding which is absolutely essential for States and communities to be able to respond to such health threats as West Nile virus, SARS, hurricanes or pandemic influenza. Now is exactly NOT the time to cut Federal preparedness funding to States and communities.

In regard to an all hazards approach, North Carolina's chemical, biological, radiological, nuclear and explosive vulnerabilities have all been assessed. On that basis, the State developed seven regional response teams to cover the entire State. These teams are comprised of a physician, nurse epidemiologist, industrial hygienists and

management support. All seven include a relationship with a veterinarian from Agriculture and three teams include a pharmacist and new lab capacity. The seven teams along with the State Preparedness and Response Team and the 85 local health departments implement the functional components of the NC Public Health Preparedness and Response Plan. This Plan includes strategies on surveillance, disease investigation, vaccination/prophylaxis, quarantine and isolation, mass care, mass fatality, public communications and command/control/communications. Every aspect of the plan is supported by critical technology systems, which are in varying stages of development or implementation. The importance of technology in saving lives cannot be underestimated. Also, the training of the workforce who must implement every aspect of the plan cannot be underestimated. These two issues—technology and workforce preparedness—are absolutely essential to effectively deploying North Carolina's Preparedness Plan and saving lives. This type of preparedness must be done "pre-event" and must include continually exercising and improving these plans.

Specifically, in regard to workforce preparedness, within the new public health infrastructure that has been built with Federal support, there are 70 Bioterrorism Planners, 7 regional surveillance teams, 12 public health epidemiologists deployed to the largest hospitals in the State and the local public health workforce of the counties. As important as the development of new vaccines is, as critical as the rapid deployment of the Strategic National Stockpile (SNS) is, if there is not an adequately trained workforce on the ground ready to disperse these medical interventions in a timely and appropriate manner then there is no point in having SNS to begin with. The passage of S. 506 (Hagle/Durbin) is critically important. This bill will provide for scholarships and loan repayment for students entering the governmental public health workforce, an important first step in addressing the current workforce crisis in public health at a time when the challenges are greater than ever before.

Sustaining the Federal resources is essential. The States are doing an outstanding job of using these funds to build the public health infrastructure—collectively 90 percent of the States have obligated or spent their 2003 funds and 90 percent have spent or obligated the hospital preparedness funds, States have spent 98 percent of the CDC preparedness funds in 2003. There are at least 5 benchmarks that have been developed to measure accountability by various Federal or national agencies on the use of these funds. Consensus is needed on which indicators measure the entire system's ability to perform in an event. North Carolina has been successfully audited three times on the use of the CDC and the HRSA funding. It is important to note that the public continues to expect more and more protection from the local, State and Federal public health system. Sustaining Federal resources is the only way to meet that expectation. The challenges are increasing as well—the best current example being the potential for pandemic flu, which will overwhelm existing infrastructure.

Real life experiences are what count. Since 9/11 and the development of this new public health infrastructure, North Carolina has had some dramatic preparedness and response challenges. These include SARS, the smallpox immunization plan, numerous hurricanes, the vaccine flu shortage, a major outbreak of E coli, an unusual outbreak of legionnaire's disease, numerous white powder incidents and various infections that could have represented a bioterrorism event. North Carolina has also staged a number of large exercises based on main public events involving a chemical release or the plague and other exercises on food security or avian influenza. In every instance, the partnerships with law enforcement, agriculture, other first responders and providers have been essential.

Question 3. What is necessary to protect our food supply and agriculture from biodefense threats?

Answer 3. If 9/11 has taught the Nation anything, it is that it can no longer approach surveillance, early detection, mitigation, response and recovery in a fragmented way. The days of a silo division of agencies needs to be replaced with a unified approach to protecting the food chain—from the farm to the fork. Public health must join forces with Department of Agriculture, FDA, EPA and industry to address biodefense concerns.

First, each State should improve communication and coordination between all regulatory/advisory agencies and private industry. Threat intelligence must be shared with industry so they can determine vulnerability.

Secondly, States, using standardized criteria, must assess the vulnerabilities of the food and agriculture chain using a valid vulnerability assessment tool, such as CARVER + Shock. The data must then be assessed and shared with all States and

industry as appropriate to enable the system to be strengthened in accordance with the current level of threat.

Third, States must also improve their ability to conduct active surveillance and detection of pathogens or contaminants by improving connectivity and interoperability among all key stakeholders. This is essential for responding to all hazard events related to livestock, plants, food and humans. To do this States, as well as the Federal Government, must develop multi-hazard threat databases in which all vulnerability and surveillance data is placed. Accessibly to this database must be provided to appropriate law enforcement, emergency response, agriculture, and public health officials.

Underlying this cooperative work between Government and industry is the development of specific mitigation response, and recovery plans designed to reduce the overall effects and impact from any terrorist act targeting the State's food and agriculture systems. Reasonable and cost effective vulnerability/risk reduction plans tailored to the key sectors of States' food and agriculture chains that are integrated within each industry component and supported by law enforcement and security community agencies need to be developed. These plans must include local and State standards in conjunction with national standard for food and agriculture security.

State leadership in shaping Government policy on food defense and dissemination of current information on Government affairs and issues must be coordinated with other States and Federal Agencies.

It is critical to assimilate and develop training curricula for key stakeholders. An institutionalized program of food and agriculture defense and response training and exercises to better prepare emergency response teams at the State and local levels, along with integrated industry training and exercises, are needed to protect the States' food and agriculture chain.

In summary, the multiple agencies and industries involved in the food chain must integrate and coordinate their surveillance, risk vulnerability, and mitigation plans. Human health, livestock and crop protection must be viewed as a single system for the development of surveillance systems, standardized plans, and training for local, State, Federal, and industry stakeholders.

RESPONSE TO QUESTIONS OF THE COMMITTEE BY TARA O'TOOLE, M.D., MPH

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July 12, 2005.

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Hon. EDWARD KENNEDY,
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Committee on Health, Education, Labor, and Pensions,
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DEAR CHAIRMAN BURR AND SENATOR KENNEDY: Thank you for the opportunity to participate in the July 14, 2005 Roundtable entitled "When Terror Strikes—Preparing an Effective and Immediate Public Health Response," sponsored by the U.S. Senate Committee on Health, Education, Labor, and Pensions, Subcommittee on Bioterrorism and Public Health Preparedness. Your continued, bi-partisan leadership on these critical issues of national security is to be commended. I am pleased to respond to the subcommittee's written questions.

Each of the three questions addresses critical aspects of biosecurity. There has been some modest progress in each of these areas in recent years, but in spite of earnest efforts by many hard working Government officials, the Nation remains largely incapable of mitigating the consequences of a serious bioterrorist attack, or campaign of attacks or of marshalling a coherent response to a natural pandemic. The disappointing pace of advancement is due in part to the technical and managerial challenges involved.

More significantly, the strategic significance and urgency of the biothreat has not been grasped or conveyed in ways that make possible the political and budgetary sea changes needed to establish the priorities and policies and build the new sys-

tems we will need—both in the United States and internationally—to mitigate the death, suffering and social and economic disruption that will come in the wake of a large, lethal and fast-moving epidemic designed and perpetrated by a thinking enemy or by mother nature.

There is a pressing need to develop a long-term U.S. biosecurity strategy, a "vision of victory" which would, if implemented, afford the Nation protection against destabilizing epidemics. This will necessarily be a long-term project given the complexities of the threat and the scope of the systems we must prepare and build. In my written comments, I will try to address both strategic goals and more tactical, near-term priorities.

Question 1. What additional incentives or other measures will ensure timely availability of sufficient amounts of effective biodefense medical countermeasures, and is the cost of such incentives acceptable?

Answer 1. The United States should establish the strategic goal of radical accelerating the development of vaccines and medicines for the prevention and treatment of infectious disease as a top national security priority. If the current timeline of countermeasure development is maintained (approximately 10 years for small molecule drugs and 7 for biologicals), the country cannot possibly afford to maintain anything resembling an adequate national stockpile of critical therapeutics against the array of potential bioweapons, nor will we have the capacity to "surge" production of needed medicines and vaccines in times of crisis, because the cost of maintaining adequate "warm base" production capacity will prove prohibitive. Furthermore, the threat of bioengineered weapons—and the age of such weapons is upon us, not a futuristic fantasy—will require the ability to rapidly create countermeasures to unanticipated pathogens.

The extraordinary advances in biological science that are now underway is such that the goal of radical acceleration of drug development is an ambitious, but plausible project, with huge payoffs for reducing the costs of health care, spurring medical innovation and addressing the burden of infectious disease in the developing world. Such a goal would require a sustained commitment on the part of the U.S. Government as well as innovative leadership, but is, in my view, absolutely essential to U.S. national security.

Tactical, Near-Term Goals

Consider new funding approaches to support the near-term development of specific countermeasures and to promote the strategic goal of accelerating drug and vaccine development generally. More specifically, Congress could consider:

- Funding mechanisms to support the early development phase of countermeasures (the "valley of death").
- Creation of a "BioDARPA" that would invest in transformational bioresearch. Such research would be "project driven" and linked to identified national needs.
- Exploring ways to encourage the biopharma industry to invest in anti-infective R&D and to pursue accelerated drug development. It is important to understand that the biopharma industry is abandoning anti-infective R&D generally—new antibiotics and antivirals and new vaccines are simply not popular investments because they do not produce returns on investments comparable to other drugs. These financial realities, the growing problem of antibiotic resistance, and the enormous burden that premature mortality due to infectious disease levies upon the developing world are going to require that governments develop innovative approaches to anti-infective medicines and vaccines, quite apart from the imperative of creating countermeasures against biological weapons. The Sementech model that was used to ensure U.S. capacity to manufacture essential microchips may be worth examining, as are suggested schemes for creating guaranteed markets for certain vaccines etc. [See, for example, "Making Markets for Vaccines—Ideas to Action," Center for Global Development, 2005.]
- Fixing the liability problem now. Most companies will not even consider countermeasure development unless they are shielded from the potential risk associated with a vaccine or medicine that cannot be tested in large clinical trials and may be used for the first time on large, heterogeneous populations in time of grave medical need. How and whether liability concerns are handled in Biosheild II will be interpreted by the industry as a bellwether of the Government's commitment to securing effective countermeasures and will be seen by the public as a signal of the Government's faith in these products. Some federally backed compensation scheme to protect patients injured by countermeasures found faulty (through causes other than negligence) should also be enacted.
- Reviewing and clarifying the HHS/DHS process for declaring a material threat and deciding what to purchase with Bioshield funds. The current process is mysterious, disjointed, slow and inefficient. "Splitting the baby" between DHS and HHS

seems unnecessarily complicated, is causing long delays and discouraging private sector participation. Red teams or some other oversight of the threat assessment process and of HHS Bioshield acquisition process should be instituted. Expert users (e.g., experienced clinicians and hospital administrators) should have a role in determining stockpile ingredients. Agencies must be assigned appropriate resources and expertise to manage these important programs and it should be clear which executive branch programs and political appointees are accountable for progress. Without a coherent and fairly transparent process for assessing threats and determining Government investments, biopharma will not invest in countermeasure R&D and the public will not be persuaded that public funds are being well used.

• Incentives to spur investments in the development of anti-infective medicines and vaccines are almost certain to be an essential component of an effective biodefense. I do not think it is possible to produce the countermeasures needed to protect the country without the active participation of the biopharma industry—they are the ones who know how to make drugs. The cost of effective incentives will be high. If such incentives are seen as an indirect tax on health care, or are extracted from the already inadequate HHS and DHS budgets, they are likely to be unpopular with much of the public. One possible approach to allaying such anxiety is to "take" funds for countermeasure incentives from the DOD budget—any zero sum budget calculations could be traded against other national defense purchases, not extracted from vital, highly pressured health care budgets. Eventually, it will be necessary to recognize that funding countermeasure development—and most of the Nation's biodefense needs—must be accounted for as essential national security investments. It is unlikely that the scope of investments and scale of new systems that will be needed to achieve biosecurity can be marshaled unless and until such expenditures of talent and treasure are recognized as central to the Nation's security. The question is whether the country will reach this recognition before a destabilizing attack or natural pandemic occurs. The record of achievement in preparing for pandemic influenza is not encouraging.

Question 2. What is necessary to build and maintain a robust national public health infrastructure to meet future biodefense requirements?

Answer 2. For the past 4 years, the United States has spent approximately $1B annually on improving "public health preparedness." By all accounts, progress has been modest. Here too, there is a need for a strategic vision of what capacities we are trying to build, a clear sense of priorities, and a coherent approach to match Federal investments with realistic costs. It is essential to reduce the current confusion about which Federal Agency is in charge and to ensure that the accountable Federal and State offices have the resources and technical staff sufficient to manage the programs under their purview.

It would be useful to clarify the notion of "public health preparedness" by specifically identifying a few critical epidemic response capacities and considering how these might be best achieved. The preparedness demands imposed upon State and local public health departments, and upon CDC, have proven unrealistically ambitious given the resources made available and the often competing priorities of Governors and local officials. I offer the following suggestions for your consideration:

Realistically Assess the Existing Limitations of Public Health Agencies; Acknowledge the Scope of What We Must Do

For the most part, the 5,000 different "public health agencies" do not spend much time or resources on the type of tasks that will be essential to responding to bioterrorism or to natural epidemics. This is not a criticism, it is simply reality: large scale outbreaks of infectious disease have not been a big problem in the past 50 years. It will not be possible to create the "necessary infrastructure" of epidemic management by tweaking or upgrading current structures. The Nation is going to have to *build whole new systems* to manage epidemics. The sooner this is recognized and we start to plan these systems and establish priorities the less time and money will be wasted, the sooner we will begin to have a rudimentary response capacity and the more likely it will be that such investments reap peacetime, "dual-use" benefits.

Epidemiological Analysis; Advice to Decisionmakers; Communication With the Public

No entity other than governmental public health agencies is likely to have the authorities or access needed to collect and analyze information essential to managing a large, fast-moving epidemic. At present, few agencies have the necessary talent or the tools or the training to fulfill these critical tasks, upon which will depend all decisionmaking from the local level to the national command authority. Communicating with the public is also a task that must be fulfilled or greatly aided by pub-

lic health officials. It may make sense to assign a high priority to ensuring that all State health agencies meet certain standards of personnel training and are equipped with adequate information management systems and tools to carryout these critical functions.

Invest in Training and Credentialing of Public Health Officials

It is important that any such training be appropriately focused. The current emphasis within most schools of public health is on research techniques, not public health practice. For training investments to pay off there would have to be a new commitment to "professionalizing" public health training. It would make sense to make Government service a condition of support for individuals participating in such programs and to require participating schools of medicine and public health to develop the appropriate curricula and practicum experiences.

Build the Electronic Information Systems Necessary to Ensure Situational Awareness During Epidemics

Creating a national electronic health network within the medical care community is an essential component of a robust public health information network. President Bush has cited such systems as a highly desirable goal to improve medical care quality and to reduce health care costs—but current plans call for implementing such systems over the next decade, with minimal Federal investments. The United States should make the implementation of an integrated electronic health information highway a top national security priority and commit to having such a system in place within the next 5 years. In the near-term, consideration should be given to how outbreak management "modules" of a comprehensive medical and public health information system might be designed and piloted, with the goal of implementing such modules in all States within 3 years.

There is a well-recognized and urgent need to build the electronic information systems needed to manage large disease outbreaks. No public health agency has the know-how or resources to design and implement such systems on their own, nor does CDC have this expertise. Such a project must be driven by the Federal Government with significant support from the private sector and from the user communities. Functionally, such systems must link health care providers—hospitals, clinics, HMOs and individual clinicians—with public health agencies. Public health authorities must have the capacity to rapidly collect and analyze data from multiple sources—especially from the health delivery organizations and from clinicians—in near-real time and to interpret such information for clinicians, the public and elected officials.

Protecting the Well: Mass Prophylaxis, Mass Immunization

A key provision to any solution to the problem of achieving rapid distribution of drugs and vaccines to large populations in time of crisis is the active support of the Nation's Governors and Mayors. They must embrace the importance and urgency of this difficult task and be willing to expend the personal time and attention needed to bring together parties within their own jurisdictions and to broker regional solutions. Anything Congress or the Administration can do to signal and emphasize the importance of such leadership would be useful.

It could be useful to "unload" some of the burden from public health agencies by assigning more operational responsibilities to the health care organizations and other organizations in the private sector. Hospitals and HMOs generally have more institutional capacity—more people, more resources, more administrative skills, more agility—than most public health agencies, in spite of the problems and financial pressures which besiege the health care delivery sector. Moreover, dispensing drugs and giving injections is what hospitals and health care delivery companies do every day. Many State plans call for massive recruitment of local health care providers to implement mass prophylaxis or mass vaccination. It may make sense to devise incentives or to obligate all or some hospitals and HMOs to take a more proactive leadership role in planning and executing such activities. For such an approach to work, it would be essential to provide appropriate compensation to the participating health care organizations.

Also, many supermarkets, pharmacies and wholesale discounters (e.g., Costco, etc.) routinely deliver flu shots and other immunizations. Research by Onora Lien and others at the Center for Biosecurity has shown that these companies cover a huge population nationally, are in every neighborhood, maintain the infrastructure needed (parking lots, electronic registration systems, registered pharmacists and nurses) to attend to large populations, and are willing and eager to help deliver care in times of emergency. Such innovative approaches should be aggressively explored. It is hard to imagine this happening unless such responsibility is clearly assigned within the Federal Agencies.

Care of the Sick During Epidemics

Care of the sick in the wake of a bioattack or natural epidemic is obviously key to mitigating death and suffering and to communities' ability to recover. Inexplicably, this aspect of bioterrorism response has been badly neglected. The monies and Federal staff resources dedicated to hospital preparedness are minimal and progress is even more limited than in the public health arena. It is unclear if HHS or DHS is responsible for this sector, there is no identifiable political appointee in charge and there have been few efforts to reach out to hospital or clinical leaders and professional groups.

The roles and expected response capacities of the medical sector must be examined and clarified. It is impossible to imagine any effective mass casualty response that is not organized on a regional basis, yet there is no "organizing authority" charged with creating such regional collaboration or coordination. Here again, Governors and Mayors could play key roles, as could some major academic medical centers and professional organizations. My colleagues and I would be happy to provide more specific thoughts on medical preparedness if this would be helpful.

Question 3. What is necessary to protect our food supply and agriculture from biodefense threats?

Government Must Exercise—and Be Seen to Play—the Role of Honest and Reliable Protector of the United States Food Supply

Answer 3. An attack on agriculture or the food supply could have significant economic and psychological consequences, but is not likely to be a strategically destabilizing event. The consequences of such an attack would depend greatly on the Government's response. To that end, it is imperative that the U.S. Government be seen as an honest broker in these matters. The recent handling of reports of BSE in American cattle—at least as is portrayed in the press and in professional journals—is sending the signal that the Government may not be telling the truth in a timely fashion. Such impressions could reap a harsh reward if the Government finds itself in the position of trying to persuade citizens and international consumers that the danger from a real attack are over or contained. Scientifically based surveillance systems are essential to ensure the safety of the food supply and the financial competitiveness of U.S. agriculture. Such systems should be developed and deployed now. This will require the USDA assuming an active oversight role and being seen as a reliable overseer by the public.

We Need a Plan for Responding to the Most Likely Scenarios

Much was learned from the 1999 outbreak of FMD in the UK, but it is not clear that these lessons have been incorporated into U.S. response plans. Roger Breeze has presented a serious proposal that might greatly limit the adverse consequences of an attack using foot and mouth disease. This plan and other alternatives should be critically examined and red-teamed.

Thank you for this opportunity to respond to the committee's questions. I look forward to working with you and your staffs on these important issues.

Yours truly,

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